



PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Aliassghar N. Tofighi et al.	Art Unit:	3732
Serial No.:	10/027,656	Examiner:	Anuradha Ramana
Filed:	December 21, 2001	Customer No.:	21559
Title:	MACHINABLE PREFORMED CALCIUM PHOSPHATE BONE SUBSTITUTE MATERIAL IMPLANTS		

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SECOND DECLARATION OF DR. ALIASSGHAR N. TOFIGHI
UNDER 37 C.F.R. § 1.132

I, ALIASSGHAR N. TOFIGHI, declare:

1. I am a named inventor of the subject matter claimed in United States Patent Application Serial No. 10/027,656 filed on December 21, 2001.
2. I have read and understood the Office Action, dated January 5, 2004, and Lee et al., U.S. Patent No. 6,117,456 (hereinafter "Lee et al."), the reference cited by the Examiner, and, as a named inventor of the subject matter disclosed in Lee et al., I fully understand its technical content. This Declaration is presented to overcome the rejection of claims 1-13 and 16-36 under 35 U.S.C. § 103 for obviousness over Lee et al.

3. I received a Ph.D. in Material Science from the National Polytechnic Institute of Toulouse, France in 1982, specializing in the field of material science. I have over 11 years of experience in the field of calcium phosphate chemistry and bone cement biomaterials.

4. The present invention features a bone implant with high compressive strength (e.g., at least about 60 MPa) that comprises an unhydrated calcium phosphate precursor that reacts, *in vivo*, to form poorly crystalline hydroxyapatite, which is ultimately remodeled into bone (see, e.g., p. 7, lines 10-16, of the specification). As I explain in detail below, the bone implant having a compressive strength greater than 60 MPa that is described and claimed in the present application is not disclosed by Lee et al., and adjusting the hardness or compressive strength of the poorly crystalline apatitic calcium phosphate material disclosed by Lee et al. using routine methods and ordinary skill in the art would not yield the presently claimed bone implant.

5. Lee et al. discloses a cement composition that is formed by combining a calcium phosphate precursor that has been prepared by mixing calcium phosphate starting materials for 3 to 5 minutes by hand using a mortar and pestle, or by machine mixing for 1.5, 2, 5, or 10 minutes using a SPEX 8510 laboratory mill with a SPEX 8505 alumina ceramic grinding chamber, with a physiologically acceptable liquid to form a paste or putty. The paste or putty is subsequently implanted and converts to a hardened poorly crystalline hydroxyapatite *in vivo*, or hardens to a poorly crystalline hydroxyapatite *ex vivo* and is then shaped and/or implanted (see, e.g., abstract, col. 8, lines 17-20, and Examples 1-30).

6. I have prepared a poorly crystalline hydroxyapatite cement, according to the methods disclosed by Lee et al., by grinding the calcium phosphate starting materials for 10 minutes (the maximum time disclosed by Lee et al.) to form the calcium phosphate precursor, which is subsequently hydrated to produce the hardened poorly crystalline hydroxyapatite. The hardened poorly crystalline hydroxyapatite that results has a compressive strength of 10 MPa.


7. I have also prepared the calcium phosphate precursor by grinding for 30 minutes according to the methods disclosed by Lee et al. The hardened poorly crystalline hydroxyapatite

that results from hydrating this material has a compressive strength of 20-25 MPa. Increasing the grinding time beyond 30 minutes results in heat-producing friction that changes the chemistry of the raw materials and precludes formation of a poorly crystalline hydroxyapatite. Furthermore, contrary to the Examiner's assertion in the present Office Action (see, e.g., page 3), the method disclosed by Lee et al. could not be optimized to produce a bone implant having a compressive strength of at least about 60 MPa, as is recited in pending claims 1-13 and 16-36.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patents issued thereon.

Respectfully submitted,

Date: 06-10-2004


Aliassghar N. Tofighi, Ph.D.